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File Name: 05a0187p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

ETHEL CUPEK, et al.,

Plaintiffs-Appellants,

v.

MEDTRONIC, INC.,

Defendant-Appellee.

No. 04-3201

Appeal from the United States District Court
for the Southern District of Ohio at Cincinnati.
No. 97-00105—Sandra S. Beckwith, Chief District Judge.

Argued: March 10, 2005

Decided and Filed: April 21, 2005

Before: KENNEDY, MOORE, and SUTTON, Circuit Judges

COUNSEL

ARGUED: Joseph M. Callow, Jr., KEATING, MUETHING & KLEKAMP, Cincinnati, Ohio, for Appellants. Thomas M. Parker, PARKER, LEIBY, HANNA & RASNICK, Akron, Ohio, for Appellee. **ON BRIEF:** Joseph M. Callow, Jr., Louis Francis Gilligan, Gregory M. Utter, Jason M. Cohen, KEATING, MUETHING & KLEKAMP, Cincinnati, Ohio, for Appellants. Thomas M. Parker, PARKER, LEIBY, HANNA & RASNICK, Akron, Ohio, for Appellee.

OPINION

KENNEDY, Circuit Judge. Plaintiffs appeal the district court's denial of leave to amend their complaint in this product liability action and the grant of summary judgment to Defendant Medtronic, Inc. based on this court's earlier decision in *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), dismissing similar claims. We affirm the district court.

BACKGROUND

Plaintiffs collectively sued Defendant alleging defects in Defendant's pacemaker leads implanted in them or their spouses. Their cases were consolidated with *Kemp v. Medtronic, Inc.*, No. C-1-97-103, 1999 (N.D. Ohio June 27, 1997) for the purposes of discovery. After all cases were consolidated in the Southern District of Ohio and after the district court denied Plaintiffs class certification, consolidation for trial, and permissive joinder, the parties agreed to administratively close all claims save *Kemp*. That case was fully litigated and appealed. *Kemp v. Medtronic, Inc.*,

231 F.3d 216 (6th Cir. 2000) (denying the bulk of Plaintiffs' claims due to federal preemption), *rehearing and rehearing en banc denied*, No. 99-3720, 2001 WL 91119 (6th Cir. Jan. 26, 2001) (unpublished), *and cert. denied*, 534 U.S. 818 (2001).

After resolution of the *Kemp* case, Plaintiffs filed a motion to reinstate their actions and file an amended complaint to present new causes of action that federal law does not preempt, and to raise arguments that are distinguishable from the arguments made in *Kemp*. Defendant did not oppose reopening the case and moved the court to grant it summary judgment pursuant to a motion it had earlier filed at the conclusion of the *Kemp* appeal.

Plaintiffs' proposed amended complaint comprised eight counts. Counts I and II alleged post-sale "failure to warn" and post-sale "failure to recall" claims against Defendant based on "information learned after FDA review of the Model 4004/4004M PMA Supplement Applications."[1] Count III alleged that Defendant failed "to [c]omply with [f]ederal [r]equirements [c]onsistent with [s]tate [r]equirements." ("Medtronic failed to comply with applicable CFR regulations in its Model 4004/4004M PMA Supplement applications."). Count IV alleged Defendant's "Negligence Per Se" in its "failure to comply with the [Food and Drug Administrations's (FDA)] conditions of approval." Counts V through VIII reasserted claims originally plead by Plaintiffs in their original complaint with greater factual specificity.

The district court disposed of Plaintiffs' motion to amend in three separate opinions and then granted summary judgment to Defendant in a final opinion. In the first opinion, issued on December 10, 2001, the district court found that counts V through VIII were directly precluded by *Kemp*. It also found that count IV was preempted because it was, in essence, a disguised fraud on the FDA claim. The district court found that federal law preempts such claims (citing *Kemp* and *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001)). The district court additionally found that counts I and II were preempted by federal law because they would impose state requirements "different from" or "in addition to" federal requirements, thus making them futile claims. The court did, however, find that federal law did not preclude Plaintiffs' proposed count III. It granted Plaintiffs ten days to file an amended complaint alleging that sole claim.

Plaintiffs failed to file the required amended complaint within the allotted time and, instead, on January 14, 2002, requested that the court reconsider its decision. Before the court ruled on that motion, the parties requested a stay to allow them to engage in settlement discussions. The court granted the stay. After lifting the stay, on November 11, 2002, the district court denied Plaintiffs' request to reconsider its earlier decision. On December 13, 2002, Plaintiffs then requested leave to amend their complaint to allege the claim the court had previously allowed.

In its third opinion, filed on September 10, 2003, the district court denied Plaintiffs leave to amend their complaint, as previously allowed, holding that justice did not require granting Plaintiffs leave at that time, because of the opportunities given them to amend their complaint in a more timely fashion. The district court also expressed concern that Defendant would be unduly prejudiced were it to grant Plaintiffs leave to amend in view of how much time had elapsed since Plaintiffs filed their original complaint. The district court also directed Plaintiffs to show cause why it should not grant Defendant's motion for summary judgment. Finally, on January 13, 2004, after Plaintiffs filed a response to the show cause order, the district court granted summary judgment to Defendant on the remaining claims. This appeal followed.

On appeal, Plaintiffs allege three errors. First, Plaintiffs claim that the district court erred in denying them leave to amend their complaint to allege that Defendant was negligent per-se in

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[1] Paragraphs 41 and 48 of these two counts read: "These duties are independent of any obligation a manufacturer may have to comply with applicable federal regulations."

failing to comply with the FDA's conditions of approval (count IV of the proposed amended complaint). Second, Plaintiffs allege that the district court erred in denying them leave to amend their complaint to assert Defendant's post-sale failure to warn and post-sale failure to recall claims (counts I and II of the amended complaint). Finally, Plaintiffs request that this court revisit its holdings in *Kemp* (and consequently reverse the district court's denial of leave to amend for counts V through VIII). Plaintiffs did not appeal the district court's denial of leave to amend count III of the proposed amended complaint.

ANALYSIS

We review de novo the district court's determination that granting Plaintiffs leave to amend would be futile. *See Ziegler v. IBP Hog Market*, 249 F.3d 509, 518 (6th Cir. 2001). We do not find error in the district court's decision. Granting leave to amend on count IV would be futile because that count is a disguised fraud on the FDA claim. The Supreme Court and this court held that federal law preempted such claims. *See Buckman*, 531 U.S. at 347-48 (explaining that the usual presumption against preemption does not apply where the field of law is inherently federal and stating that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law"); *id.* at 349 n.4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.") (quoting 21 U.S.C. § 337(a)); *Kemp*, 231 F.3d at 236.

Federal law also preempts proposed amended counts I and II because those counts would impose state requirements "different from" or "in addition to" the federal requirement. *See* 21 U.S.C. § 360k(a) ("no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."). As recognized in *Kemp*, the FDA requires continuous updates as part of the pre-market approval (PMA) application and supplement process. *Kemp*, 231 F.3d at 221-22. These updating requirements specifically address warnings and recalls associated with medical devices. *See* 21 U.S.C. § 360h(a) (giving the Secretary of Health and Human Services the authority to issue or withhold warnings concerning medical devices based on the Secretary's assessment of the risks); *id.* § 360(e)(1) (giving the Secretary authority to order manufacturers to cease distributing devices upon a finding they could cause "serious, adverse health consequences or death"); *id.* § 360h(e)(2)(a) (giving the Secretary authority to issue recall orders); 21 C.F.R. § 803.50 (requiring device manufacturers to report adverse medical device events to the FDA); *id.* § 810.10 (giving the FDA discretion to determine if a recall is necessary and to decide to delay public notification to avert health risks). Any claim, under state law, then, that Defendant failed to warn patients beyond warnings required by the FDA, or that Defendant failed to recall a product without first going through the PMA supplement process would constitute state requirements "different from" or "in addition to" the requirements of the federal PMA application and supplement process. *See* 21 U.S.C. 360k(a); *see also Kemp*, 231 F.3d at 235. Such requirements would, therefore, not "parallel federal safety requirements . . . ." *Buckman*, 531 U.S. at 353.[2] Plaintiffs' proposed amended claims themselves undermine their preemption arguments, because those claims assert that Defendant has duties "independent of any obligations . . . to comply with applicable federal regulations." Such independent duties are, at the very least, "in addition to" federal requirements, and may very well

[2] There appears to be significant disagreement between the parties over whether Minnesota or Ohio law applies to this dispute. That question is irrelevant to our disposition of these issues. Federal law would preempt Plaintiffs' claims regardless of whether Minnesota or Ohio law applied.

be "different from" federal requirements. Thus, federal law preempts proposed amended counts I and II because those counts would require Defendant to comply with state requirements "different from" or at least "in addition to" federal requirements. Plaintiffs' request to amend was futile.

Finally, Plaintiffs ask us to revisit our holding in *Kemp*. We may not do so. "A panel of this Court cannot overrule the decision of another panel. The prior decision remains controlling authority unless an inconsistent decision of the United States Supreme Court requires modification of the decision or this Court sitting en banc overrules the prior decision." *Salmi v. Secretary of Health and Human Services*, 774 F.2d 685, 689 (6th Cir. 1985). Plaintiffs cite no authority that would allow us to revisit this court's earlier holding. We hold, therefore, that the district court did not err in denying Plaintiffs leave to amend, because the proposed amendments are futile as described by the district court, this court in *Kemp*, and the Supreme Court in *Buckman*.

CONCLUSION

For the foregoing reasons, we **AFFIRM** the decision of the district court.